

REMARKS

The specification has been amended to insert sequence identifiers for the sequences in Figure 9 and to remove hyperlinks.

An electronic form of a substitute sequence listing is attached to this Amendment. The substitute sequence listing has been revised to include the sequences found in Figure 9 and to update the application information.

Claims 1 and 3 have been amended to specify the stringent hybridization conditions. Support for the stringent hybridization conditions can be found in paragraph 92.

Claim 1 has been further amended to specify that the nucleic acid meeting these hybridization conditions also has 90% identity to the nucleic acid encoding the polypeptide of SEQ ID NO:5. Support for this identity language can be found in paragraph 92 which recites the technically incorrect term of “homology.”

Claim 3 has been further amended to specify that the nucleic acid meeting these hybridization conditions also has 90% identity to respective nucleic acid of SEQ ID NOs:1, 2, 3 or 4. Support for this identity language can be found in paragraph 92 which recites the technically incorrect term of “homology.”

Claims 7, 12 and 29 have been amended to specify that the plant promoter is a “plant **functional** promoter.” (emphasis added) Support for this language can be found in paragraphs 47 and 52-55. These paragraphs describe promoters that are functional in plants, including bacterial promoters, viral promoters and eukaryotic promoters, including plant promoters.

Claim 12 has further been amended to conform to U.S. patent practice.

Claims 22 and 23 have been canceled in view of the foregoing amendments.

New claims 35 and 36 have been added to specify that the identity is 95%. Support for this identity language can be found in paragraph 92 which recites the technically incorrect term of “homology.” These new claims read on the elected invention.

It is submitted that these amendments do not constitute new matter and their entry is requested.

Applicants note that the Examiner made the restriction final. In this context, Applicants note that the present application is a national stage filing of a PCT application and as such are entitled to claims directed to a product and process in the same application. Hence, the method claims have not been canceled at this stage and have been amended to reflect amendments made in the product claims. In addition, Applicants submit that the special technical feature of the present invention is a nucleic acid that encodes a polypeptide having the amino acid sequence of SEQ ID NO:5 and nucleic acids that hybridize under stringent conditions (as specified in the claims) to this nucleic acid and that confers resistance to *Xanthomonas*. Applicants submit that this special technical feature is not anticipated by Zhang et al. Since the present invention defines a contribution over the art, it does contain a special technical feature as defined by PCT Rule 13.2, Applicants submit that the method claims should be rejoined with the product claims should the product claims be found to be allowable in accordance with the PCT rules.

The Examiner objected to the specification for the presence of hyperlinks and lack of sequence identifiers for the sequences in Figure 9. The specification has been amended to insert sequence identifiers and to remove the hyperlinks. These amendments obviate this objection.

The Examiner rejected claims 1, 3 and 5-18 under 35 U.S.C. § 112, first paragraph for lack of written description. In essence, the Examiner contends that the specification does not describe a representative number of species of nucleic acids that are greater than 50 nucleotides that (a) hybridize to the specified nucleic acids and (b) have the specified activity to demonstrate that the inventors were in possession of the broad genus of nucleic acids. The Examiner also contends that there is no structure/function description in the specification that could provide an alternative description of the invention. Applicants submit that the amended claims fully comply with the written description requirement.

First, Applicants note that claims 6-8 are withdrawn claims and claims 9-10 and 14-18 were previously canceled. Second, the Examiner references nucleotide sequences comprising at least 100 contiguous bps but does not include claim 22 in this rejection, although Applicants note that claim 22 has been canceled by the present amendment. Third, claims 1 and 3 have been amended to

specify the stringent hybridization conditions set forth in the specification and to specify that such stringently hybridizing nucleic acids have 90% (or 95%) identity with the original nucleic acid. In addition, language concerning 50 nucleotides or 100 nucleotides have been deleted from the claims. Fourth, the written description can be complied with by describing the claimed invention using words. *See, Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir.1997) (“[a]n applicant complies with the written description requirement ‘by describing the invention, with all its claimed limitations, not that which makes it obvious,’ and by using ‘**such descriptive means as words**, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.’” (emphasis added)); *Lockwood v. American Airlines Inc.*, 107 F.3d 1565, 41 USPQ2d 1961 (Fed. Cir. 1997). Applicants have described the isolated nucleic acid by both structure and function, i.e., a nucleic acid that encodes the polypeptide of SEQ ID NO:5 and a nucleic acid that hybridizes to this nucleic acid under specified stringent hybridization conditions, is 90% identical to this nucleic acid and provides a plant with resistance to *Xanthomonas* when transfected to the plant. This description, in combination with the four sequences provided in the specification, clearly demonstrates to a skilled artisan that Applicants were in possession of the claimed invention as set forth in the claims and described in the specification.

Furthermore, Applicants submit that the specification fully describes a nucleic acid that encodes the polypeptide of SEQ ID NO:5, i.e., the specification fully describes the invention of claim 5 and its dependent claims. Applicants have provided the complete amino acid sequence for the polypeptide of SEQ ID NO:5. The provision of this complete sequence puts “one in possession of the genus of DNA sequences encoding it and, that one of ordinary skill in the art ... may have therefore have been in possession of the entire genus of DNA sequences that encode the disclosed” polypeptide. *In re Wallach*, 378 F.3d 1330, 1333, 71 USPQ2d 1939, 1942 (Fed. Cir. 2004).

In view of the above amendment and remarks, Applicants submit that the specification fully describes the claimed subject matter. Withdrawal of this rejection is requested.

The Examiner rejected claims 1, 3, 5, 11-13, 22 and 25-30 under 35 U.S.C. § 112, first paragraph for lack of enablement. In making this rejection, the Examiner first contends that the

specification does not provide enough evidence to demonstrate that the polypeptide of SEQ ID NO:5 is responsible for resistance to *Xanthomonas* and is thus the Xa31 gene. This contention is based on three points: (1) the specification shows that the coding regions are the same between the resistant and susceptible alleles, (2) the specification says that the expression patterns are similar and (3) the specification teaches that the functional terminators are identical between the two alleles. The Examiner also contended that the specification is not enabling for nucleic acids (a) greater than 50 bps that hybridize under stringent conditions to a nucleic acid encoding the polypeptide of SEQ ID NO:5 and provide resistance to *Xanthomonas*, (b) comprising at least 100 contiguous bps and provide resistance to *Xanthomonas* or (c) nucleic acids that hybridized to nucleic acids of SEQ ID NOs:1-4 under stringent conditions and provide resistance to *Xanthomonas*. A major reason for this contention was that there was no requirement as to identity between the nucleic acid sequences and those that hybridized to them under stringent hybridization conditions. Applicants submit that the amended claims are fully enabled by the specification.

First, Applicants agree that the specification shows that the coding regions of the *Xa31* candidates are identical between the resistant and the susceptible alleles. That is, the resistance (dominant) allele in IRBB31 and the susceptible (recessive) allele in IR24 carry identical coding region of the *Xa31* candidates. In fact, the two alleles carry identical transcriptional region - the regions that are bigger than the coding regions of the *Xa31* candidates. As known in the art, the phrases "the resistance (dominant) allele in IRBB31" and "the susceptible (recessive) allele in IR24" are named or called relatively based on their reaction to a certain *Xoo* pathogen. For example, the resistance (dominant) allele in IRBB31 is a resistance allele (and is induced) when the plant is infected by *Xoo* strain PXO99. However, it will not be a resistance allele (and is not induced) when IRBB31 is infected by another *Xoo* strain AXO1947. Similarly, the susceptible (recessive) allele in IR24 is a susceptible allele (and is not induced) when the plant is infected by PXO99. But it may become a resistance (dominant) allele (and be induced) when IR24 is infected by an unidentified *Xoo* strain.

Second, although the specification in paragraph 84 would suggest that maybe there is no difference in expression patterns, Applicants submit that the remainder of the specification clearly demonstrates that the coding region imparts resistance to *Xanthomonas* in transgenic plants. Specifically, the specification shows the mapping, cloning and sequencing of the resistance allele and the identification of the coding sequence in Examples 1-7. Example 6 describes complementation studies and genomic cloning of the resistant allele. These studies demonstrated that the cloned using the cloned resistant allele imparted resistance to *Xanthomonas* in transgenic plants. Example 7 describes the isolation of cDNA clones from a cDNA library that was used for screening for the expressed genes in the resistant and susceptible alleles. The cDNA that was isolated encodes the protein of SEQ ID NO:5. As stated in Example 7, no other expressed region within the resistant allele was found. Thus, Applicants submit that the specification clearly teaches that the polypeptide of SEQ ID NO:5 is the polypeptide sequence that imparts resistance to *Xanthomonas*.

Third, as mentioned above, the two alleles carry identical transcriptional region. The transcriptional region includes the functional terminator. Also as mentioned above, the resistance specificity of the two alleles is determined by **the promoters of the two alleles** and **the avirulence (Avr) proteins** from the pathogens and has nothing to do with Xa31 protein or its terminator.

The specification clearly teaches that Applicants isolated the *Xa31* gene by positional cloning strategy and transformation approaches. Genetic complementation mapped the *Xa31* gene to the 5198-bp genomic clone from IRBB31. Only one gene or transcriptional unit was identified in the 5198-bp region. As the transcriptional unit was activated upon inoculation with incompatible pathogens, the encoded protein from the mRNA transcript should be the Xa31 protein.

As discussed above, the specification clearly teaches a skilled artisan that the polypeptide of SEQ ID NO:5 imparts *Xanthomonas* resistance to plants. Thus, nucleic acids encoding this polypeptide are fully enabled by the specification. In addition, the specification also teaches that promoters heterologous to the coding region can be operatively linked to the coding region for the polypeptide of SEQ ID NO:5. See, for example, paragraph 47. In view of the teachings in the

specification, a skilled artisan would reasonably predict that such constructs would impart resistance to *Xanthomonas* in transgenic plants. Applicants have confirmed this prediction in Gu et al. (“*R* gene expression induced by a type-III effector triggers disease resistance in rice,” *Nature* **435**:1122-1125, 2005; copy attached). With respect to Gu et al., Applicants note that the name of the gene changed from *Xa31* to *Xa27*. However, a comparison of the polypeptide sequence and promoter regions of the alleles show that they are indeed the same genes.

Fourth, the claims have been amended to delete reference to any nucleic acid of 50 or 100 bps that imparts resistance of plants to *Xanthomonas*. The claims have further been amended to specify the stringent hybridization conditions and have been amended to specify that any nucleic acid hybridizing under these specified conditions has 90% (or 95%) identity with the original nucleic acid. Finally, the claims also require that such nucleic acids provide a plant with resistance to *Xanthomonas*. Thus, the scope of the claims has been significantly reduced and specifically excludes the unpredictable aspects noted by the Examiner at pages 9-11 of the Office Action. Applicants submit that there is no undue experimentation (nor has the Examiner established any) for a skilled artisan to screen the nucleic acids that meet the hybridization and identity limitations of the claimed subject matter for the specified property of imparting resistance to a plant to *Xanthomonas*. Although some experimentation may be necessary, it is clear that such experimentation is not undue to a skilled artisan in view of the teachings in the specification.

In view of the above amendment and remarks, Applicants submit that the specification fully enables the claimed subject matter. Withdrawal of this rejection is requested.

The Examiner rejected claims 1, 3, 5, 11-13, 22, 26-27 and 29-30 under 35 U.S.C. § 102(b) as being anticipated by Zhang et al. (*Nature Biotech* **17**:1021-1024, 1999). The Examiner contends that Zhang et al. anticipates the present invention because the stringent hybridization conditions are not described in the specification and because “a” polypeptide of SEQ ID NO:5 reads on any sequence derived from SEQ ID NO:5. Applicants submit that the amended claims are not anticipated by Zhang et al.

Specifically, the Examiner is incorrect concerning the stringent hybridization conditions. These conditions are set forth in paragraph 92 of the specification. Claims 1 and 3 have been amended to incorporate these stringent hybridization conditions. Claim 5 has been amended as suggested by the Examiner to obviate this rejection. In addition, Applicants have compared the sequence of *albD* to *Xa31*. There is no homology (identity) between the two genes either at the DNA level or the amino acid level. Thus, Applicants submit that the nucleic acid of Zhang et al. does not hybridize under the specified stringent hybridization conditions to a nucleic acid encoding the polypeptide of SEQ ID NO:5. Consequently, Zhang et al. does not and cannot anticipate the claimed subject matter.

In view of the above amendments and remarks, Applicants submit that Zhang et al. does not anticipate the claimed subject matter. Withdrawal of this rejection is requested.

The Examiner has rejected claims 1, 3, 5, 11-13, 22, 26-27 and 29-30 under 35 U.S.C. § 102(b) as being anticipated by Sasaki et al. (GenBank Accession No. AP003623, 2001). Applicants submit that the Examiner is in error in this rejection.

Specifically, Claim 5 has been amended as suggested by the Examiner to obviate this rejection. Claims 1 and 3 have been amended to incorporate the stringent hybridization conditions specified in the specification and have been amended to specify that the nucleic acids that hybridize under stringent hybridization conditions have 90% (or 95%) identity with the original nucleic acid. Sasaki et al. does not disclose these limitations and thus cannot anticipate the claimed subject matter.

In addition, Applicants note that the original sequence submitted to GenBank by Sasaki et al. did not contain any identification of coding regions in the genomic clone. The identification of coding regions only occurred in the submission that was made available to the public on 27 July 2004, after the effective filing date of the present application, i.e., after 13 August 2003. In the absence of the identification of coding regions in the genomic clone, there is no disclosure in Sasaki et al. of the polypeptide having the amino acid sequence of SEQ ID NO:5. Proof that Sasaki et al. did not disclose the polypeptide is shown in the attached documents printed from the GenBank website. The first document is the Revision history for AP003623. This document shows the

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history for the Sasaki et al. submissions. The second document is the printout of the version with the 11 May 2001 update date. The third document is the printout of the version with the 21 March 2002 update date. The fourth document is the printout of the version with the 8 April 2004 update date. The fifth document is the printout of the version with the 27 July 2004 update date. The sixth document is the printout of the version with the 10 August 2006 update date. This evidence shows that Sasaki et al. did not disclose any polypeptide sequence prior to the effective filing date of the present application. Consequently, Sasaki et al. does not and cannot anticipate the claimed subject matter.

In view of the above amendments and remarks, Applicants submit that Sasaki et al. does not anticipate the claimed subject matter. Withdrawal of this rejection is requested.

In view of the above amendments and remarks, Applicants believe that the present claims satisfy the provisions of the patent statutes and are patentable over the cited prior art. Reconsideration of this application and early notice of allowance is requested. The Examiner is invited to telephone the undersigned if it will assist in expediting the prosecution and allowance of the instant application.

Respectfully submitted,

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ATTACHMENTS: Electronic Form of substitute Sequence Listing
Gu et al., “*R* gene expression induced by a type-III effector triggers disease resistance in rice,” *Nature* **435**:1122-1125, 2005.
Revision history for AP003623
AP003623: version with 11 May 2001 update date

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